



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 27 1999 9 42 4 '99 JUN -2 P1:22

De Lois L. Shelton
Regulatory Compliance
Weider Nutrition International, Inc.
2002 South 5070 West
Salt Lake City, Utah 84104-4836

Dear Ms. Shelton:

This is in response to your letter of April 27, 1999, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Weider Nutrition International, Inc. is making the following claim, among others, for the product:

Sinus Free™ Two Phase System:

“Sinus Free’s...[t]o help your body maintain optimal health even when exposed to pollen and other foreign element.”

Your submission also states that Weider Nutrition International, Inc. is marketing a product called **GAN Cold-Free Brand Echinacea**. 21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for the product Sinus Free, and the name of the product “Cold-Free,” suggest that they are intended to treat, prevent, or mitigate disease, namely, allergies (caused by pollen and other foreign elements) and the common cold. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

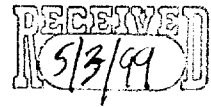
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file, r/f)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605 (Bowers)
HFV-228 (Benz)
HFV-232 (Brown)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:5/4/99
Init:GCF-1:ABarnett:5/25/99
f/t:HFS-456:rjm:5/25/99:docname:64909.adv:disc37

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA



In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **GAN Cold-Free Brand Echinacea Product #53130 & #53135** bearing the statements set out below:

Weider Nutrition International., Inc.
2002 South 5070 West
Salt Lake City, Utah 84104

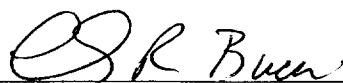
The text of each structure-function claim for *Echinacea purpurea* & Goldenseal (*Hydrastis canadensis*) is as follows:

- | | |
|----------------------|--|
| (Statement 1) | Immune System Support |
| (Statement 2) | Echinacea and Goldenseal nutritionally support healthy immune system function. |

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International., Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 27th day of April, 199 9.

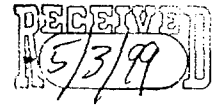
WEIDER NUTRITION INTERNATIONAL, INC.

BY: 
DR. LUKE R. BUCCI
Vice President of Research

Also see dock

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NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA



In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **Weider Sinus Free Two Phase System Product #52505** bearing the statements set out below:

Weider Nutrition International., Inc.
2002 South 5070 West
Salt Lake City, Utah 84104

The text of each structure-function claim for **Zinc, Zhi Shi, Tylophlora indica/asthmatica & Adhatoda vasica** is as follows:

- (Statement 1) Zinc Lozenges to support a normal immune system.
- (Statement 2) Herbal Capsules to promote a health respiratory system.
- (Statement 3) Sinus Free's two phase system provides all-natural ingredients to help your body maintain optimal health even when exposed to pollen and other foreign element.

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International., Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 27th day of April, 199 9.

WEIDER NUTRITION INTERNATIONAL, INC.

BY:

A handwritten signature in cursive script, appearing to read "L R Bucci".

DR. LUKE R. BUCCI
Vice President of Research

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